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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,980	09/05/2003	Stanten C. Spear	P0011669.00	8939

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EXAMINER	
LAMPRECHT, JOEL	
ART UNIT	PAPER NUMBER
3737	
MAIL DATE	DELIVERY MODE
09/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/655,980	SPEAR ET AL.	
	Examiner	Art Unit	
	JOEL M. LAMPRECHT	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/18/08 has been entered.

Claim Objections

Claims 1-43 are objected to because of the following informalities: Regarding claims 1, 16 and 33, it is unclear how a delivery device can be advanced to an area corresponding to a first site, and then further advanced to the site in a second or additional step if the device is advanced to the area already. Regarding claims 2 and 17 it is unclear how the contrast medium and distal end relate to the medium and distal end which is set forth in the independent claims. Regarding claims 5-7 and 20-22, "the area along the first site" lacks antecedent basis. Regarding claims 12-14, 27-29, 32, 33, 42, and 43, the claims appear to be directed to structural limitations and fail to set forth additional steps within the method; additionally, claims 13, 28, and 33 are directed to a method step of making the device. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-43 rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al. in view of Niazi (US 6,638,268 B2). Rosenman et al. disclose a catheter drug delivery system used for locating a target site for delivering therapy to a patient comprising advancing a delivery device with steerable portion and deflectable portion which tapers for delivery of drugs to a first site through a lumen (also dual lumen forms) in fluid communication with a thru lumen and delivering contrast media from the distal end of the delivery device within the first site (Fig 8-10, Col9 Line 38-Col 10 Line 24). Additionally Rosenman et al. disclose advancing a guidewire within a patient and advancing the delivery device (Col 3 Line 40-Col 4 Line 14) to the area along the first

site via a guide catheter before advancing the delivery device to the area along the first site through and outward from the guide catheter, and later advancing the guide catheter again over the delivery device (Col 4 Line 49 - Col 5 Line 7). Also Rosenman et al. disclose a single shaft lumen with multiple lumen portions offset from each other but still in fluid communication through the use of Luer fittings (Fig 8-9, Col 8 Line 15 – Col 9 Line 4). Finally Rosenman et al. disclose advancing a guide wire outward form the distal end through the thru lumen of a delivery device within the first site and advancing the delivery device over the guide wire, and the deflectable tip includes outer wall and inner wall forming a tip lumen in fluid communication with the thru lumen and has a distal opening at the top (Col 13 Line 25-56). The delivery device has an outer diameter of less than 7 French in embodiments and tapers along its length to less than 6 French. The deflectable portion of the delivery catheter shaft has a Pebax material which becomes more deflectable towards the distal end of the delivery unit, eventually hitting 35D (Col 9 Line 19 – Col 9 Line 62). The additional form of therapy suggested by Rosenman et al consists of extending a wire through the lumen of the catheter guide system to test for penetration of the myocardium (Col 4 Line 15-50).

Rosenman et al. do not disclose the delivery of a pacing lead to the target over the guide wire itself. Rosenman et al. additionally do not disclose a gradual taper, rather they disclose a component taper over the length of the tip region. Finally, Rosenman et al do not disclose specific angiography techniques as claimed regarding the flow of the contrast medium injected. Attention is paid to the secondary reference by Niazi which discloses a gradual taper towards the distal end of the central lumen

allowing for a end diameter of 5 French and contains a tip lumen suitable for delivery of contrast media as well as disclosure of a hydrophilic guidewire system (Claim 1, Col 2 Line 15-40, Col 5 Line 29-65, Col 4 Line 15-35). Niazi also discloses the retraction of the fluid delivery system (Col 4 Line 35-55, Col 5 Line 29-60) and specifically mentions the coronary sinus as the target site (Claim 24). Finally, Niazi discloses methods for cardiac angiography including a fluoroscopic injection procedure for imaging and locating both transverse and coronary sinus components via fluoroscopic injection (and of course inherently the observation of the "flow" of the contrast agent) (Col 2 Line 15-55, Col 3 Line 10-55). It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the gradual taper and pacing lead delivery system of Niazi with the contrast media delivery system of Rosenman et al as Rosenman et al disclose in Col 4 Line 15 – 50 that electrical monitoring with a wire placed at the distal tip of the catheter delivery system is an important measure of penetration of the myocardium.

Rosenman et al. do not disclose using a PEBA material with jet milled tungsten carbide or using a non-braided section, rather they use a braided stainless steel variation which starts and comprises the range of Applicant's Durometer ratings from 72D to 40D to 35D reading. The selection of jet milled tungsten carbide and non-braided stainless steel on the second portion is a design choice and would have been obvious to one of ordinary skill in the art at the time of the invention.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al US 6,004,269 in view of Niazi US 6,638,268 B2) and in further view of

Leiden et al (US 6,297,220 B1). As disclosed above Rosenman et al in view of Niazi disclose a steerable delivery device within the body and for use of locating a target site via a contrast injection, but does not specifically mention the location of the coronary sinus ostium by the flow of the contrast media and by that locating advancing the device upstream into the coronary sinus. Attention is then directed to the secondary reference by Leiden et al which discloses the use of fluoroscopic-injection based guidance of a catheter into the coronary sinus ostium. It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the methods of Leiden et al for the location of the coronary sinus ostium with the contrast-injection navigation methods of Rosenman et al in view of Niazi for the purpose of treating and locating the coronary sinus ostium (Leiden et al Col 11 Line 55- Col 12 Line 20).

Response to Arguments

Applicant's arguments filed 6/18/08 have been fully considered but they are not persuasive. Regarding the argument that Rosenman teaches confirming a location, but not navigating to or locating a location, the Examiner respectfully disagrees and asserts (as does Rosenman in Col 3 Line 40 - Col 4 Line 50) that repositioning to another location, should the first location be deemed unsatisfactory, is performed using a contrast agent, though the new rejection incorporating the teachings of Niazi is relied upon for the teaching of the specific angiography procedure as details are lacking on the steps in the Rosenman et al reference. Regarding the argument that Rosenman must "locate the target site" before advancing or positioning a device in that target site,

Examiner agrees, but fails to see how the claims as written do not require a knowledge of a "location of a target site" in order to begin any sort of injection procedure. The terms "first site" and "target site" are not specific enough to denote any relationship other than an order of location. No relative position, etc is implied by these terms, and thus angiography, even that with a balloon occlusion and saline rinse will yield diagnostic information about the location of one site and sites flowing down or upstream away from that location. It is well-presumed and hopefully common knowledge to cardiologists, the anatomy of the cardiac system, in particular of the coronary sinus (Gray's Anatomy, ISBN 0-443-07168-3). A fluoroscopic injection in the sinus, as disclosed within Niazi gives way to location of target sites either up or downstream of the injection (See Col 2 Line 15-55, Col 3 Line 10-55 for a discussion of both transverse and coronary sinus components as eventual targets after fluoroscopy). The arguments levied against the Leiden et al reference, mainly that Leiden does not disclose location of the coronary sinus ostium through observation of the flow of contrast within an atria away from the ostium, Examiner directs attention to Col 8 line 20-42, wherein the pathway for locating the coronary sinus ostium is described (under fluoroscopic guidance) as including a pathway from an external jugular vein (or carotid artery) and advanced up to the coronary sinus ostium.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is

(571)272-3250. The examiner can normally be reached on Monday-Friday 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

JML